References:

 Sassolas G, Garry J, Cohen R, Bastuji H, Vermeulen E, Cabrera P, Roussel B, Jouvet M. Nocturnal continuous infusion of growth hormone (GH)-releasing hormone results in a dose-dependent accentuation of episodic GH secretion in normal men. Clin Endocrinol Metab. 1986 Oct;63(4):1016-22.

Abstract

Fluctuations in plasma GH levels have been found in patients with acromegaly who have continuously elevated levels of ectopically produced GH-releasing hormone (GHRH). Likewise, plasma GH fluctuations have been found in normal subjects receiving continuous GHRH infusions. We report the effects of two doses of GHRH, administered by constant infusion, on nocturnal GH secretion in six normal young men. Each received, in random order, 2.5 ng/kg X min GHRH, 15 ng/kg X min GHRH, and 0.15 M NaCl. During both GHRH doses, a highly significant increase in total nocturnal GH secretion was found (P less than 0 001) as well as an increase in GH secretion during different periods of the night. Nocturnal GH secretion was episodic during the GHRH infusions, with an increase in the number and magnitude of the peaks compared to those during the NaCl infusion. Plasma immunoreactive GHRH concentrations plateaued at 1 h during the high dose and at 3 h during the low dose GHRH infusion. Sleep parameters, including total sleep time, sleep latency, and duration and timing of the different sleep stages, were not affected by GHRH infusions. We conclude that GHRH, continuously infused, increases nocturnal GH secretion according to the dose, while the episodic pattern of GH secretion is maintained.

 Treatment effects of intranasal growth hormone releasing peptide-2 in children with short stature. Pihoker C, Badger TM, Reynolds GA, Bowers CY. J Endocrinol. 1997 Oct;155(1):79-86.

Abstract

Growth hormone-releasing peptide (GHRP)-2 is a synthetic six amino acid peptide that is a potent GH secretagogue. Although it shares no structural homology with GHreleasing hormone, in clinical studies its actions on the pituitary release of GH are similar. It is effective when administered orally and intranssally. For children with GH deficiency, such noninvasive treatments are most desirable and in need of development. Fifteen children with short stature participated in this study. All of the children had a height < 2 S.D. below mean for age, poor height velocity, delayed bone age, and low serum concentrations of IGF-1. These children had been tested with standard GH secretagogues, e.g. arginine, insulin, and L-dopa. Fifty percent of the children were GH deficient, the remainder had idiopathic short stature. The children received testing with GHRH and GHRP-2 as an acute i.v. bolus of 1 microgram/kg; all children in this study demonstrated a GH response > 20 micrograms/l Each child in this study also demonstrated a GH response > 10 micrograms/l in response to intranasal GHRP-2, in the dose range of 5-20 micrograms/kg. The children were administered intranasal GHRP-2, 5-15 micrograms/kg, twice a day for 3 months, then three times a day. Fifteen children participated in the study for 6 months; six of the children have participated for 18-24 months. Height velocity, serum IGF-1, IGF-binding protein 3 (IGFBP-3) and GHbinding protein (GHBP) concentrations, and GH responses to GHRP-2 by i.v. bolus and

intranasal spray were examined during treatment. Height velocity increased from 3.7 +/-0.2 cm/year to 6.1 +/- 0.3 cm/year at 6 months, 6.0 +/- 0.4 cm/year at 18-24 months. There were no significant changes in IGF-1 or IGF-PB3 concentrations, or in acute GH responses to i.v. or intranasal GHRP-2. GHBP concentrations rose significantly, from 439 +/- 63 pmol/l to 688 +/- 48 pmol/l. In this study, intranasal GHRP-2 administration was well tolerated, and produced a modest but significant increase in growth velocity.

 Isadori A, Lo Monaco A, Cappa M. A study of growth hormone release after oral administration of amino acids. Curr Med Res Opin. 1981 7(7):475-481.

<u>Abstract</u>

A study was carried out in 15 male volunteers to evaluate qualitatively the secretion of growth factors following stimulation by oral amino acids. The results showed that oral administration of a combination of two amino acids (1200 mg I-lysine plus 1200 mg of I-arginine) provoked a release of pituitary somatotropin and insulin. This phenomenon was reproducible and the growth hormone secreted in response to this stimulation had biological activity (as demonstrated by a radioreceptor assay and somatomedin induction). The effect appeared to be specific to the combination of the two amino acids; neither of the amino acids demonstrated appreciable stimulating activity when administered alone, even at the same doses.

4. Welbourne TC. Increased plasma bicarbonate and growth hormone after an oral glutamine load. Am J Clin Nutr. 1995 May;61(5):1058-61.

Abstract

An oral glutamine load was administered to nine healthy subjects to determine the effect on plasma glutamine, bicarbonate, and circulating growth hormone concentrations. Two grams glutamine were dissolved in a cola drink and ingested over a 20-min period 45 min after a light breakfast. Forearm venous blood samples were obtained at zero time and at 30-min intervals for 90 min and compared with time controls obtained 1 wk earlier. Eight of nine subjects responded to the oral glutamine load with an increase in plasma glutamine at 30 and 60 min before returning to the control value at 90 min. Ninety minutes after the glutamine administration load both plasma bicarbonate concentration and circulating plasma growth hormone concentration were elevated. These findings demonstrate that a surprisingly small oral glutamine load is capable of elevating alkaline reserves as well as plasma growth hormone.

5. Kasai K, Kobayashi M, Shimoda SI. Stimulatory effect of glycine on human growth hormone secretion. Metabolism. 1978 Feb;27(2):201-8.

Abstract

Glycine (250 ml 0.3 M glycine) was administered orally to 19 nonobese normal subjects and 12 subjects with partial gastrectomy. In the normal subjects, a clear and significant increase of serum human growth hormone (hGH) level was observed (p less than 0 001), whereas serum immunoreactive insulin (IRI), prolactin (PRL) and blood sugar (BS) levels were not affected after the drug administration. A more pronounced and significant increase of hGH value in serum was found in the subjects with gastrectomy

than in the normal controls (p less than 0.001). Thus we administered the drug intraduodenally in normal subjects. The similar rise of hGH to that of the gastrectomied group was obtained in normals by this administration. The facts demonstrated that glycine is one of the stimulatory agents inducing the pituitary gland to secrete hGH. In addition, in nonobese diabetics, no significant increase of serum hGH level, even after the intraduodenal administration of glycine, was observed in the present study.

6. Blum A, Cannon RO 3rd, Costello R, Schenke WH, Csako G. Endocrine and lipid effects of oral L-arginine treatment in healthy postmenopausal women. J Lab Clin Med. 2000 Mar;135(3):231-7

Abstract

As a substrate for nitric oxide synthesis, L-arginine may give the same protection as estrogen, but its other biologic effects may adversely affect atherogenesis. Therefore, possible endocrine and lipid effects of L-arginine were investigated in a double-blind, placebo-controlled, single crossover study. After randomization, oral L-arginine (9 g) or placebo was given daily for 1 month, with crossover to the alternate therapy after a 1month washout period, to 10 postmenopausal women receiving no estrogen. Compared with placebo, L-arginine increased growth hormone (1.5+/-1.8 mg/L vs. 0.6+/-0.6 mg/L, P = 04) but had no effect on insulin and catecholamines. Total cholesterol, triglyceride, apolipoprotein E, and low-, very-low-, and high-density lipoprotein cholesterol levels were also unaffected. Lipoprotein(a) measured by an immunoturbidimetric method was increased by L-arginine in 9 of 10 women relative to placebo (0.46+/-0.35 g/L vs. 0.38+/-0.30 g/L, P = .053), and the changes in lipoprotein(a) levels significantly correlated with the relative increase in growth hormone (r = 0.85, P = .03). However, lipoprotein(a) measured by an enzyme-linked immunosorbent assay failed to demonstrate significant changes Lack of an increase by L-arginine in lipoprotein(a) with a verifiable apolipoprotein(a) isoform-independent method, despite an increase in growth hormone, questions the validity of previous observations for growth hormone-induced increases in lipoprotein(a). The observed lack of effect on major endocrine hormones and lipid profile support the safety of oral L-arginine administration.

CURRICULUM VITAE

NAME: Frank L. Greenway III, M.D.

Pennington Biomedical Research Center

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ACADEMIC RANK: Professor

EDUCATION:

1970 M.D.

University of California at Los Angeles

School of Medicine

1966 B.A., Biology

Stanford University

MILITARY:

Major, United States Army National Guard, Medical Corps, California, 1970-1977

CERTIFICATIONS:

California License # G21213, 1971 Louisiana License # 11090R, 1995 American Board of Internal Medicine License # 43764; 1973, 1980, 1987 American Subspecialty Board of Endocrinology and Metabolism License #43764,1975

PROFESSIONAL EXPERIENCE:

1997 - Present	Adjunct Professor, Human Ecology Department, Louisiana State University,
	Baton Rouge, LA
1996- Present	Clinical Professor of Medicine, Department of Medicine, Louisiana State
	University Medical Center, New Orleans, LA
1995 - Present	Medical Director and Professor, Pennington Biomedical Research Center,
	Louisiana State University, Baton Rouge, LA
1993 - 1995	Clinical Professor of Medicine, UCLA School of Medicine, Los Angeles, CA
1986 - 1986	Preceptor for third year medical student, College of Osteopathic Medicine of
	the Pacific, Pomona, CA
1985 - 1993	Associate Clinical Professor of Medicine, UCLA School of Medicine, Los
	Angeles, CA
	G v v

1976 - 1984	Director of Medical Education for third and fourth year clinical clerks from Autonomous University of Guadalajara Medical School, Guadalajara, Mexico,
	Marina Mercy Hospital, Marina Del Rey, CA
1977 - 1985	Assistant Clinical Professor of Medicine, UCLA School of Medicine, Los
	Angeles, CA
1975 - 1977	Instructor of Medicine, UCLA School of Medicine, Los Angeles, CA
1973-1975	Chief Resident, Endocrinology, and Fellow, Metabolism, Harbor-UCLA
	Medical Center, Los Angeles, CA
1971-1973	Internal Medicine residency, Harbor-UCLA Medical Center, Los Angeles, CA
1970-1971	Rotating internship, Harbor-UCLA Medical Center, Los Angeles, CA

PROFESSIONAL ORGANIZATION MEMBERSHIPS:

- 1. American Diabetes Association, 1975 present
- 2. American College of Physicians (Fellow), 1975 present
- 3. North American Association for the Study of Obesity, 1977 present
- 4. International Association for the Study of Obesity, 1977 present
- 5. The Endocrine Society, 1993 present
- 6. American Society for Nutritional Sciences, 1990 present
- 7. American Society for Clinical Nutrition, 1990 present
- 8. East Baton Rouge Parish Medical Society, 1995 present
- 9. American Association of Clinical Endocrinologists, 1995 present
- 10. American Society of Bariatric Physicians, 1997 2000

Editorial Board:

Obesity Update. 1985 - 1988

GRANTS AND CONTRACTS:

Funded:

- 1. Sterling Drug Co. Study of aspirin and fertility, 1974 (PI)
- 2. Squibb Drug Co. Study of the effects of CCK ctapeptide on food intake, 1975 (PI)
- 3. American Society of Bariatric Physicians. Study of the effects of HCG on weight loss, 1975 (PI)
- 4. Mead-Johnson Pharmaceutical Co. Study of the effects of benzbromarone on uric acid and gout, 1976 (PI)
- 5. Bayer Pharmaceutical Co. Study of acarbose and its effects on weight loss in type 2 diabetes, 1981 (PI)
- 6. Center for Fiber Research. Comparison study of glucomannan and other fibers in type 2 diabetes, 1982 (PI)
- 7. Bayer Pharmaceutical Co. Study of acarbose and its effects on type 1 diabetes, 1983 (PI)
- 8. E.R. Squibb & Sons Inc. Evaluation of captopril in hypertensive patients, 1983 (PI)
- 9. Thompson Medical Co. Study of the effect of pseudoephedrine on weight loss, 1984 (PI)

- 10. Miles-Bayer Pharmaceutical Co. Study of the effects of bay-1099 on type 1 diabetes, 1984 (PI)
- 11. Miles-Bayer Pharmaceutical Co. Study of the effects of acarbose on obese type 2 diabetic subjects, 1987 (PI)
- 12. Sandoz Pharmaceutical Co. Clinical trial of a lipolysis cream, 1987 (PI)
- Thompson Medical Co. Study of the effects of phenylpropanolamine caplets on obese subjects, 1987 (PI)
- Miles-Bayer Pharmaceuticals, Inc. Study of the effects of acarbose on insulin-requiring, type 2 diabetics, 1987 (PI)
- Miles-Bayer Pharmaceuticals, Inc. Study on acarbose versus tolbutamide in dietcontrolled type 2 diabetics, 1988 (PI)
- 16. Miles-Bayer Pharmaceuticals, Inc. Study of the effects of acarbose on type 1 diabetics, (PI)
- 17. Pharmakinetics-Bolar Pharmaceutical Co., Inc. Comparison study of tolazamide, glyburide and glipizide in diet-controlled type 2 diabetes, 1988 (PI)
- 18. Pharmakinetics-Bolar Pharmaceutical Co., Inc. Insulin reduction trial in non-insulin dependent type 2 diabetics, 1989 (PI)
- 19. Thompson Medical Co. Controlled comparison of phenylpropanolamine, benzocaine and their combination in the treatment of obesity, 1990 (PI)
- 20. Pharmaco-Sandoz Pharmaceutical Corp. Open-label assessment of the safety and efficacy of isradipine in the treatment of patients with mild to moderate hypertension, 1990 (PI)
- 21. Lederle Laboratories. Open label study of sustained release verapamil in patients with hypertension, 1990 (PI)
- 22. Pharmaco-Synergen, Inc. Multicenter double-blind evaluation of recombinant human basic fibroblast growth factor in the treatment of diabetic ulcers, 1991 (PI)
- 23. Miles Pharmaceuticals, Inc. Multicenter double-blind comparative study of the long-term (one year) safety of BAY-g-5421 (acarbose) versus placebo in the treatment of insulin dependent (type 1) and non-insulin dependent (type 2) diabetes mellitus, 1991 (PI)
- 24. Ortho-McNeil Pharmaceutical Corp. Clinical surveillance study of ofloxacin, 1991 (PI)
- 25. Boots Pharmaceuticals Inc. Six month, dose-ranging, placebo-controlled study of sibutramine for the treatment of obesity, 1992 (PI)
- Hoffman LaRoche Pharmaceuticals, Inc. Two-year, two-dose, placebo-controlled study of orlistat for the treatment of obesity, 1992 (PI)
- 27. TFH Cosmetics. Clinical trial of lipolysis cream, 1992 (PI)
- 28. Sandoz Pharmaceutical, Inc. Dose-ranging study of the effect of guar gum and chromium on postprandial glucose and insulin levels, 1992 (PI)
- 29. Procyte Corporation. Clinical trial of lamin for diabetic neuropathic foot ulcers, 1993 (PI)
- 30. Sandoz Pharmaceutical, Inc. Clinical trial of fluvastatin for hypercholesterolemia, 1993 (PI)
- International Pain Research Institute. Clinical trial of geranium oil bourbon for topical treatment of peripheral neuropathy, 1993 (PI)
- 32. KAL Center for Nutritional Research. Trial to test the effectiveness of Diet Max™ in increasing metabolic rate, 1993 (PI)
- 33. International Pain Research Institute. Clinical trial of 2% aminophylline cream for local fat reduction, 1993 (PI)
- 34. International Pain Research Institute. Clinical trial of .5% aminophylline cream for local fat reduction, 1993 (PI)
- Boots Pharmaceuticals, Inc. Multicenter, open-label, flexible-dose study to evaluate the long-term effects of sibutramine in obese patients, 1993 (PI)

- 36. Magnetic Resonance Diagnostics. Controlled trial of the magnetic resonance analyzer for neck and back pain, 1994 (PI)
- 37. Cerenex Pharmaceuticals. Postmarketing surveillance trial of sumatriptan for migraine headaches, 1994 (PI)
- 38. NaturalMax Company. Controlled double-blind crossover trial of DietMax on oxygen consumption, 1995 (PI)
- Warner-Lambert. Double blind controlled crossover trial of topical geranium oil for postherpetic neuralgia, 1995 (PI)
- 40. Amgen Inc. Characterization of serum leptin concentrations in the general adult population, 1995 (PI)
- 41. NIH(NHLBI). Efficacy of diet therapy in subjects at risk for CHD, 1997 (Co-PI)
- 42. Chiralt Corp. Do intracellular minerals predict the progression of impaired glucose tolerance to diabetes mellitus, 1997 (PI)
- 43. Ergo Science Development Corp. A study to evaluate the safety and efficacy of varying dosages of timed medications in the treatment of obesity, 1997 (PI)
- 44. Hoechst Marion Roussel, Inc. Evaluating HOE 901 insulin in subjects with type 2 diabetes, 1998 (PI)
- Weight Watchers. Comparing the efficacy of the weight watchers program vs. self-help program, 1998 (PI)
- 46. Amgen, Inc. A phase 2, multi-center, randomized, placebo-controlled study to evaluate the efficacy and safety of subcutaneously administered recombinant-methionyl human-Fc-Leptin (r-metHu-Fc-Leptin) in obese subjects, 1998 (PI)
- 47. Roche Laboratories/Covance Inc. A double-blind randomized comparison of the efficacy and safety of 52 weeks of xenical plus diet in the treatment of obesity in periand post-menopausal women at cardiovascular risk, 1998 (PI)
- 48. Roche Laboratories. A 52-week, double-blind, randomized, placebo-controlled study to evaluate the efficacy of orlistat treatment in obese patients with type 2 diabetes, 1998 (PI)
- 49. Novartis Pharmaceutical Corp. A twenty-eight week, double-blind and observer-blind to lipid values, active-controlled, randomized, parallel-group, multicenter study to assess the safety and efficacy of fluvastatin slow release (80 mg) administered once daily at bedtime in patients with primary hypercholesterolemia compared to lescol 40 mg, 1998 (Co-PI)
- 50. NIH(NHLBI). Premier: lifestyle interventions for blood pressure control, 1998 (Co-PI)
- 51. Parke-Davis Pharmaceutical Research. Clinical study of troglitazone, 1998 (Co-PI)
- 52. Schering-Plough Research Institute. A pilot study to assess quality of life changes with ecopipam in obese subjects, 1999 (PI)
- 53. NIH (NIDDK). Study of health outcomes of weight loss (Look AHEAD) trial, 1999 (Co-PI)
- 54. Regeneron Pharmaceuticals, Inc. The screening protocol for: a double-blind, randomized, placebo-controlled safety and dose finding study of axokine in severely obese subjects AX15-OB-9907, 1999 (Co-PI)
- 55. Bristol-Myers Squibb. A multicenter, randomized, double-blind, placebo-controlled, parallel study of the efficacy and safety of metformin hydrochloride for the treatment of pediatric subjects with type 2 diabetes mellitus, 1999 (PI)
- Glaxo Wellcome, Inc. A parallel, three-arm, blinded, placebo-controlled study to evaluate the safety, tolerability and pharmacokinetics of GW320650 in healthy obese subjects, 1999 (PI)

- 57. Regeneron Pharmaceuticals, Inc. double-blind, randomized, placebo-controlled safety and dose finding study of axokine in severely obese subjects - AX15-OB-9908, 2000 (Co-PI)
- 58. GlaxoWellcome, Inc. A multicenter, randomized, double-blind, placebo-controlled, parallel-group study to investigate the tolerability and efficacy of oral 1555U88 (2.5 mg. 5 mg, 10 mg, or 15 mg per day) compared to placebo for the treatment of obesity in subjects 18-65 years of age, 2000 (PI)
- 59. Amgen, Inc. A randomized, double-blind, placebo-controlled study to evaluate the change in body weight during treatment with subcutaneously administered A-200 after VLCD-induced weight loss in obese subjects, 2000 (PI)
- 60. GlaxoWellcome, Inc. Bupropion-SR weight-loss (management center), 2000 (PI)
- GlaxoWellcome, Inc. Bupropion-SR weight-loss (study site), 2000 (PI) 61.
- 62. Schering-Plough Research Institute. A phase III multi-center, two arm study to assess the efficacy and safety of ecopipam (SCH 39166) in the management of obesity, 2000 (PI)
- 63. Roche Laboratories. The effect of orlistat on the intake of dietary fat, 2000 (PI)
- 64. Knoll Pharmaceuticals. A 12-month study to assess the safety and efficacy of meridia (sibutramine hydrochloride monohydrate) 10 and 15 mg in obese adolescents (SB 238), 2000 (Co-PI)
- 65. Amgen, Inc. The effect of leptin A-200, caffeine/ephedrine and their combination upon weight loss and body composition in man. 2000 (PI)
- 66. LSU/Sub/BoR. Development of crude extracts for use as; herbal dietary supplements to prevent cancer and high blood pressure, 2000 (Co-PI)
- 67. R.W. Johnson Pharmaceutical Research Institute (Parexel). A randomized, doubleblind, placebo-controlled, multicenter, parallel group, dose-response study to assess the efficacy and safety of topiramate in the treatment of subjects with obesity, 2000 (Co-PI)
- 68. Knoll Pharmaceuticals. The effect of combination therapy of meridia (sibutramine hydrochloride monohydrate) and meal replacement on body weight and weight loss maintenance in obese individuals, 2000 (PI)
- Regeneron Pharmaceuticals, Inc. A phase III, 12-month double-blind, randomized, 69. parallel group, placebo-controlled, efficacy and safety study of axokine in overweight and obese subjects with a 12-month open-label extension phase, 2000 (Co-PI)
- 70. PPD Development. Omapatrilat cardiovascular treatment assessment versus enalapril (OCTAVE), 2000 (PI)
- 71. Science, Toxicology and Technology. Herbal caffeine and ephedrine, 2000 (PI)
- 72. Archer Daniels Midland. The effect of soy pasta on satiety in humans, 2001 (PI)
- 73. GlaxoSmithKline. A randomized, single-dose crossover study evaluating the effect of coadministration of food and various pre-loads on the pharmacokinetics and food intake following a single oral dose of 24mg of GI181771X as a tablet in healthy, overweight subjects, 2001 (PI)
- 74. LSUHSC - Transneuronex. The effects of the implantable gastric stimulator (IGS) on food intake and change in body composition: an ancillary study, 2001 (PI)
- 75. Proctor and Gamble. A randomized, parallel, open-label, multicenter study to evaluate and characterize weight loss associated with 12 weeks use of a nutritional beverage containing ethyl oleate as a meal replacement, 2001 (Co-PI)
- 76. Sanofi-Synthilabo. A randomized, double-blind, placebo-controlled, parallel-group, fixed-dose, multicenter study of weight-reducing and prevention of weight regain effects and safety of SR141716 in obese patients with or without comorbidities (RIO-North America) (PI)

- 78. The American Phytotherapy Research Laboratory. The effect of ingesting the protein, VVYP, on stool calories, (PI)
- 79. Pennington Biomedical Research Center. Safety of adding catechins to more than 8 weeks of caffeine and ephedrine treatment, (pilot study), 2001 (PI)
- 80. Archer Daniels Midland. Effect of diacylglycerol on the respiratory quotient, thermogenesis and energy expenditure, 2002 (PI)
- Epitome Pharmaceuticals. New Geranium Oil Formulation for the Treatment of 81. Neuropathy Pain, 2002 (PI)
- 82. Muscle Tech Research and Development Inc. The effect of ephedra and epigallocatechin gallate with caffeine on oxygen consumption in man, 2002 (PI)
- 83. Pennington Biomedical Research Center. The effect of adding ephedra to epigallocatechin gallate and caffeine on resting metabolic rate, 2002 (PI)
- 84. Nutricia USA. A randomized, double-blind clinical study to evaluate the safety and thermogenic effect of an herbal supplement compared to placebo in healthy adults. 2002 (PI)
- 85. GlaxoSmithKline. An eight-week, parallel group, double-blind, randomized, placebo and active-controlled, multicenter study to evaluate the efficacy, safety and tolerability of two formulations of GI181771X, each at two different doses, in obese subjects, 2002 (PI)
- 86. Community Foundation for Southeast Michigan. The long-term safety and efficacy of caffeine and ephedrine with or without catechins, and the acute effect of superimposed catechins and tyrosine on metabolic rate, 2002 (PI)
- 87. Community Foundation for Southeast Michigan, Expression Profiling: A novel technique to subtype the obese patient and predict response to obesity therapy. 2002; Steven Smith (PI), Frank Greenway (Co-PI)
- 88. Pfizer Inc. Food intake measurements for the assessment of anorectic drugs, 2002 (PI)
- 89. Pennington Biomedical Research Center, Pilot protocol testing a new waist-cord design for weight maintenance, 2002 (PI)
- Pennington Biomedical Research Center. Pilot study of the safety and efficacy of the 90. Chinese herbal decoction [Nt] for weight loss, 2002 (PI)
- 91. Novartis Pharmaceuticals Corp. Randomized, double-blind, placebo-controlled, dosefinding, multicenter study of Sandostatin LAR® Depot (20 mg, 40 mg, 60 mg) in patients with primary insulin hypersecretion (PIH) and at least moderate obesity, 2002 (PI)
- 92. Glaxo-Smith-Kline. A 16-week, randomized, double-blind, placebo-controlled, parallelgroup two-site study to investigate the efficacy and tolerability of 400 mg/day of bupropion SR compared to placebo for the treatment of adolescent obesity, 2002 (PI)
- 93. NIH (NIA). Metabolic adaptations to two-year caloric restriction, 2002 (Co-PI)
- Metabolite. A double-blind, randomized, placebo-controlled trial to test the safety and 94. efficacy of two doses of the Chinese herbal decoction [Nt] enriched in gallic acid for weight loss [Nt-3], 2003 (PI)
- 95. Health and Nutrition Technologies, Inc. Pilot Protocol Testing a New Diet Belt Design for Weight Maintenance, 2003 (PI)
- 96. Pennington Biomedical Research Center. Pilot study of the safety and efficacy of the Chinese herbal decoction [Nt] enriched in gallic acid for weight loss, 2003 (PI)
- 97 Ross Products Division-Abbott Laboratories. Effect of long-term ingestion of dietary diacylglycerol on body fat composition and metabolic parameters in subjects with type 2 diabetes or markers of the insulin-resistant metabolic syndrome, 2003 (PI)
- Nutricia. Constructing a tyramine dose response curve, 2003 (PI) 98.
- 99. Harkness Pharmaceuticals, Inc. Determination of normal enterostatin levels to a meal challenge, 2003 (PI)

- Harkness Pharmaceuticals, Inc. A pilot study to determine the dose of enterostatin 100. needed in the obese to raise low enterostatin levels to those of normal healthy controls, 2003 (PI)
- Ferring Pharmaceuticals, Inc. A multi-center, open-label, randomized, single-dose, two-101. period crossover study to compare the bioavailability of the proposed U.S. commercial formulation of the menotropin for injection (U.S. Menopur®) relative to that of menotropin for injection marketed in Europe (Eu Menopur®) in healthy adult female subjects, 2003 (PI)
- Nutricia. The effect of caffeine, catechins and yerba mate on metabolic rate, appetite 102. and body weight, 2003 (PI)
- Nutricia. The safety and efficacy of phenylephrine for increasing metabolic rate and 103. causing weight loss, 2003 (PI)
- Labrada Nutrition. Pilot study of an ephedra-free dietary herbal supplement for weight 104. loss, 2003 (PI)
- Phytomedics. Efficacy and safety of PMI-5011 in subjects with type 2 diabetes mellitus 105. not optimally controlled with diet and exercise or monotherapy: A 4-month, doubleblinded, randomized, placebo-controlled, parallel comparative trial, 2003 (Co-PI)
- Pfizer Inc. A one-year, open, randomized, parallel, three-arm study comparing exubera 106. (insulin dry powder pulmonary inhaler) vs. avandia (rosiglitazone maleate) as add-on therapy vs. exubera substitution of sulfonylurea in patients with type 2 diabetes, poorly controlled on combination sulfonylurea and metformin treatment, 2003 (Co-PI)
- Glaxo-Smith-Kline. A parallel, six-month, double-blind, randomized, placebo-controlled, 107. multicenter, dose-ranging study to evaluate the efficacy, safety and tolerability of orally administered GI181771X on weight loss in overweight and obese subjects. GSK protocol no. CKA20001, 2003 (PI)
- 108. Archer Daniels Midland. Effect of diacylglycerol on metabolic rate, fat oxidation, serum triglycerides, free fatty acids and ketones, 2003 (PI)
- 109. Pfizer, Inc. A study to examine the effect of olanzapine on indices of food intake, glucose metabolism and energy expenditure Inc., 2003 (PI)
- General Nutrition Corporation. Determining the glycemic index of food, 2003 (PI) 110.
- Washington University, Regulation of intestinal cholesterol absorption, 2003 (Co-PI) 111.
- Metabolife. Active medication extension to the double-blind, randomized, placebo-112. controlled trial of two doses of the Chinese herbal decoction (Nt) enriched in gallic acid for weight loss, 2003 (PI)
- 113. Takeda Pharmaceuticals, Inc. A portion control diet will prevent weight gain in diabetes treated with ACTOS, 2003 (Co-PI)
- Pennington Biomedical Research Center. Does weight loss inhibit angiogenesis?, 2004 114.
- General Nutrition Corporation. The effect of a dietary herbal supplement containing 115. caffeine, catechins and verba mate on metabolic rate, appetite and body weight, 2004
- Pennington Biomedical Research Center. A pilot study of a topical non-prescription 116. treatment for psoriasis, 2004 (PI)
- Metabolife. Pharmacokinetic study of gallic acid from gall nut extract and Nt mixed with 117. gallic acid from gall nut extract, 2004 (PI)
- Acceleration Therapeutics. Pilot study of AT-101 for the treatment of obesity and insulin 118 resistance, 2004 (PI)
- GlaxoSmithKline. A parallel, six-month, double-blind, randomized, placebo-controlled, 119. multicenter, dose-ranging study with a double-blind, placebo-controlled, eighteen-month

- extension to evaluate the efficacy, safety and tolerability of orally administered GI181771x on weight loss in overweight and obese subjects, 2004 (PI)
- 120. Light Heart, LLC. Effect of a rice bran bar with N-3 fatty acids and vitamins on serum lipids, 2004 (PI)
- 121. Orexigen Therapeutics, Inc. Phase 2, multicenter, randomized, blinded, placebocontrolled, proof of concept study of combination therapy for safety and efficacy in subjects with uncomplicated obesity (OASIS-1), 2004 (Co-PI)
- Orexigen Therapeutics, Inc. Phase 2, multicenter, randomized, double-blind, placebocontrolled, proof of concept study of combination therapy for safety and efficacy in subjects with uncomplicated obesity (OASIS-2), 2004 (PI)
- Almond Board of California. The effect of almonds on weight loss and weight maintenance: a 12-month, randomized, controlled study in overweight and obese subjects, 2004 (Co-PI)

Pending

1. NIH/National Center for Complementary and Alternative Medicine. Obesity and antiangiogenic pomegranate fruit extract. \$400,000; 2004 [Zhijun Liu (PI), Frank Greenway, David York (Co-PIs)]

HONORS AND AWARDS:

- 1. Doffelmeyer Scholarship for Eagle Scouts, Stanford University, 1962-1966
- 2. Student Research Award, Second Place, UCLA School of Medicine, 1968
- 3. Alumni Award, UCLA School of Medicine, 1970
- 4. Merit Award, Los Angeles Surgical Society, 1973
- 5. Distinguished Teaching Award, Department of Medicine, Harbor-UCLA Medical Center, 1986

INVITED SPEAKER AT MAJOR CONFERENCES AND SYMPOSIA:

- 1. University of the Pacific. Obesity, 1974.
- California Employee Pharmacists Association, Obesity, 1975.
- 3. Martin Luther King Hospital. Obesity, 1975.
- 4. Hyatt Hotel. Nutrition, 1976.
- 5. Harbor General Hospital. Third factor, 1976.
- 6. Good Samaritan Hospital. Treatment of obesity, 1977.
- 7. Harbor General Hospital. Obesity and drug treatment, 1978.
- 8. Harbor General Hospital. Surgical treatment of obesity, 1979.
- 9. American Diabetes Association, Southern California Affiliate. Protein sparing diets, 1982.
- 10. Vicar International Seminar. New medical treatment for obesity, 1983
- 11. Harbor General Hospital. Practical treatment of obesity, 1983.
- 12. Harbor-UCLA Medical Center, grand rounds. Obesity treatment, 1984.
- 13. Weigh To Go Inc., Valley Presbyterian Hospital. Treatment of obesity, 1984.
- Weight Loss Clinic International Annual Meeting. Treatment of obesity, Detroit, Michigan, 1984.

- 15. Martin Luther King-Charles Drew Medical Center, grand rounds. Obesity treatment, 1985.
- 16. Continuing Medical Education for Pharmacists, Professional Seminars. Obesity treatment, Buena Park, Inglewood and Millbrae, CA, Las Vegas, NV, 1985.
- 17. UC Riverside Medical Student Course on Endocrinology and Metabolism, Harbor-UCLA Medical Center. Protein calorie malnutrition and obesity, 1985.
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- 40. Heshka S, Greenway F, Miller-Kovach K, Pi-Sunyer FX. Structured commercial weight loss program improves homocysteine levels compared to self-help weight loss. FASEB J 13:A269, 1999.
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- 44. Greenway FL, Morales S, DeLany JP, Bray GA. Causes of error in methods for determining body composition during weight loss. Presented at the NAASO Annual Meeting, Charleston, SC, 1999.
- 45. Sothern M, Gordon S, Greenway F, Blecker U, Udall C, Udall J. A family-based, multidisciplinary treatment program reduces body mass index in obese 5 to 7 year olds. Presented at the NAASO Annual Meeting, Charleston, SC, 1999.
- 46. White MA, Whisenhunt BL, Williamson DA, Greenway FL. The food craving inventory and implications for weight loss treatment. Presented at the NAASO Annual Meeting, Charleston, SC, 1999.
- 47. Williamson DA, Womble LG, Zucker NL, Reas DJ, White MA, Blouin DC, Greenway F. Body image assessment for obesity (BIA-O): development of a new measure. Poster presentation at the NAASO Annual Meeting, Charleston, SC, 1999.
- 48. Heshka S, Anderson JW, Atkinson RL, Phinney SD, Greenway F, Hill JO, Miller-Kovach K, Pi-Sunyer FX. Self-help weight loss versus a structured commercial program after 1 year: a randomized controlled study. FASEB J 14(4):37, 2000.
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- 50. Heshka S, Anderson JW, Atkinson RL, Greenway F, Hill JO, Phinney S, Miller-Kovach K, Pi-Sunyer FX. A randomized, controlled 2-year study of self-help weight loss compared with a structured commercial program. Presented at the Annual NAASO Meeting, Long Beach, CA, October 29-November 2, 2000.
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- Martin C, Williamson D, Mickley N, Greenway F. Food cravings and consumption of a high fat, high sugar food: gender and ethnic differences. Presented at the Annual NAASO Meeting, Long Beach, CA, October 29-November 2, 2000.
- 54. Anderson JW, Greenway F, Fujioka K, Gadde K, McKenney J, O'Neil P. Bupropion SR significantly enhances weight loss when used with a moderate-intensity lifestyle intervention. Presented at the Annual NAASO Meeting, Long Beach, CA, October 29-November 2, 2000.
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- Heshka S, Anderson JW, Atkinson RL, Greenway F, Hill JO, Phinney S, Miller-Kovach K, Pi-Sunyer FX. Self-help weight loss vs a structured commercial program: a two-year randomized controlled trial. Presented at the Annual NAASO Meeting, Quebec City, Canada, October 7-10, 2001.
- 57. de Jonge L, Frisard M, Blanchard D, Greenway F. Safety and efficacy of an herbal dietary supplement containing caffeine and ephedra for obesity treatment. Presented at the Annual NAASO Meeting, Quebec City, Canada, October 7-10, 2001.

- 58. Anderson JW, Greenway F, Fujioka K, Gadde K, McKenney J, O'Neil P. Bupropion SR significantly enhances weight loss when used with a moderate-intensity lifestyle intervention: a 48-week study. Presented at American Diabetes Association, Philadelphia, PA. Diabetes 50:A21, 2001.
- 59. White MA, Whisenhunt BL, Williamson DA, Greenway FL, Netemeyer RG. Development and validation of the food-craving inventory. Exp Biol Med 227(2):105-107, 2002.
- 60. Anderson JW, Greenway F, Fujioka K, Gadde K, McKenney J, O'Neil P. Bupropion SR significantly enhances weight loss when used with a moderate-intensity lifestyle intervention: a 48-week study. Presented at Nutrition Week, San Diego, CA. Am J Clin Nutr 75(2)379S, 2002.
- 61. Miller-Kovach K, Heshka S, Anderson J, Atkinson R, Greenway F, Hill J, Phinney S, Pi-Sunyer X. Biological indices from a 2-year, randomized controlled trial of weight loss with self-help vs a commercial program. Presented at Nutrition Week, San Diego, CA, February, 2002.
- 62. Ravussin E, Williamson D, de Jonge L, Caglayan S, Thaw JM, Walden H, Wong ML, Tataranni PA, Wagner A, DiPaoli A, Greenway F, Ozata M, Alvarado I, Licinio J. Effects of human leptin replacement on food intake and energy metabolism in three leptin-deficient adults. Presented at the annual Endocrine Society Meetings, San Francisco, CA, June, 2002.
- 63. Greenway F, Smith S, Fujioka K. A-200, a long-acting leptin analog, does not enhance fat, visceral fat, or weight loss when combined with caffeine and ephedrine in obese subjects. Presented at the 9th International Congress on Obesity, Sao Paulo, Brazil, August, 2002.
- Roberts AT, de Jonge L, Parker C, Greenway F. The effect of black tea extract and caffeine (TeaLean) on oxygen consumption in man. FASEB J 17(4):A328, 2003.
- 65. Reas DL, Williamson DA, Greenway F, Raum B, Fujioka K, Bethancourt I, Stewart L, Blanchard D, Arnett C, Walden H, Thaw J, Antolik E. Relationship between weight loss and body image in obese females seeking weight loss treatment. Presented at the 2003 International Conference on Eating Disorders. Omni Interlocken Resort, Denver, CO, May 29-31,2003.
- 66. Martin C, Greenway F, White M, Ortego L. The effect of ecopipam on food cravings and binge eating pathology during a six-month weight loss trial. Obes Res 11:395-P;Sept 2003.
- 67. Martin C, Greenway F, O'Neil P, Anderson J, Fujioka K, Gadde K, McKenney J, White M. The effect of bupropion on food craving over 24 weeks in a multicenter weight loss trial. 11-402-P;Sept 2003.
- Taylor A, Fountaine R, Martin C, Mancuso J, Greenway F. Reproducibility of food intake measurements and early detection of efficacy of anorectic drugs. Presented at NAASO 2003 Annual Meeting, Ft. Lauderdale, FL, October 11-15. Obes Res 11:405-P;Sept 2003.
- 69. Lustig R, Greenway F, Velasquez P, Heimburger D, Schumacher D, Smith D, Smith W, Soler N, Zhu W, Hedrick J, Hohneker J. Weight loss in obese adults with insulin hypersecretion (IH) treated with sandostatin LAR® depot. Presented at the 2003 Annual Scientific NAASO Meeting, Ft. Lauderdale, FL, October 11-15, 2003.
- 70. Fujioka K, Sheard J, Greenway FL, Stewart L. Fresh grapefruit causes weight loss. Presented at the 2004 American Diabetes Association Meeting, Orlando, FL, (hot topic) June 4-8, 2004.
- 71. Martin C and Greenway FL. Diolean, an ephedra-free dietary herbal supplement, reduces fat craving and intake of calories, fat, and carbohydrate. Presented at The

- Endocrine Society 86th Annual Meeting, New Orleans, LA, June 16-19, 2004. Program and Abstracts, Endocrine Society Press, Chevy Chase, MD. P2-350:391.
- Fujioka K, Greenway F, Sheard J. The effects of grapefruit on weight and insulin 72. resistance: relationship to the metabolic syndrome. Presented at the 64th Scientific Sessions, Orlando, FL, June 4-8, 2004. Diabetes 52:A594, 2004.

INVENTIONS AND PATENTS:

Granted:

- 1 Greenway FL and Bray GA. Treatment for selective weight control. U.S. Patent No. 4,525,359 issued June 25, 1985.
- Greenway FL and Bray GA. Treatment for selective weight control. U.S. Patent No. 2. 4,588,724 issued May 13, 1986.
- Greenway FL and Bray GA. Potato chip having no added fat or globular protein. U.S. 3. Patent No. 5,952,026 issued September 14, 1999.
- Greenway FL and Rood JC. Method and Composition for Delivering Therapeutically 4. Effective Amounts of Pyruvate to a Mammal. U.S. Patent No. 6,417,231 issued July 9, 2002.

Pending:

- 1. Greenway FL, Liu Z, Woltering E. Inhibition of angiogenesis and destruction of angiogenic vessels with certain plant extracts, gallic acid and its derivatives. Filed May 27, 2004. Serial no. PCT/US04/16647, filed May 28, 2003 (File no. 02P01W Greenway).
- 2. Greenway FL, Roberts AT. Waist Chain and Related Method, U.S. Patent Application Serial No. 10/713,518; U.S. Patent and Trademark Office, filed November 14, 2003 (File # 15894/099042-00).

SERVICE:

Committee Assignments:

International

Chairman, North American Association for the Study of Obesity Clinical Committee

National

Obesity Research Network Executive Committee

Local

Institution

Institutional Review Board, Louisiana State University Safety Committee, Pennington Biomedical Research Center

Grant Reviewing

- 1. John Sealy Memorial Endowment Fund, 2001
- Department of Veterans Affairs, Research and Development Committee, Lexington VA Medical Center, 2002

Consultant Positions

- 1. Jenny Craig, Medical Advisor and Chairman, Medical Advisory Board
- 2. Health and Nutrition Technology, Medical Advisory Board
- 3. GlaxoSmithKline, Obesity Advisory Board
- 4. General Nutrition Corporation, Medical Advisor
- 5. Orexigen, Clinical Development
- 6. Nastech Pharmaceutical Company, Inc., Medical Advisor
- 7. ABIC International Consultants, Inc., Medical Advisor for obesity project
- 8. The RAND Corporation, Medical Advisor

Clinical Services

Provide medical support for approximately one-half of the patients in clinical studies and on-call approximately one-half of each year.

Ad Hoc Manuscript Reviewer

- 1. American Journal of Clinical Nutrition
- 2. American Journal of the Medical Sciences
- 3. Annals of Internal Medicine
- 4. British Journal of Clinical Pharmacology
- 5. Clinical Pharmacology and Therapeutics
- 6. Diabetes Care
- Endocrine Practice
- 8. European Journal of Clinical Nutrition
- 9. Expert Opinion on Drug Safety
- 10. Food and Chemical Toxicology
- 11. International Journal of Obesity and Related Metabolic Disorders
- 12. Journal of the American Medical Association
- 13. Mayo Clinic Proceedings
- 14. Nutrition
- 15. Obesity Research
- 16. Obesity Surgery
- 17. Pediatrics
- 18. Southern Medical Journal

Conference Organization

Obesity Research Network Meeting, Baton Rouge, Louisiana, March 1999

TEACHING:

Courses Taught

- Lecturer for course no. 7029 Woody Medicinal Plants, course instructor Zhijun Liu, Louisiana State University, Baton Rouge, LA, 1999
- Lecturer at ethics seminar, instructor Forest Smith, FDS Consulting and Counseling, Louisiana State University (NSF REU), Baton Rouge, LA, 2003
- Lecturer at Men's Health Day, Knapp Hall, Louisiana State University, Ag Center, Baton Rouge, LA, 2003
- 4. Lecturer for course no. HUEC 4021, course instructor Prithiva Chanmugam, Louisiana State University, Baton Rouge, LA, 2004
- Lecturer at ethics seminar, instructor Forest Smith, FDS Consulting and Counseling, Louisiana State University (NSF REU), Baton Rouge, LA, 2004

Theses and Dissertation Committees

- 1. Denae Drab, M.S. degree, Department of Psychology, Louisiana State University, Baton Rouge, LA
- 2. Roshaun Mathews, M.S. degree, Department of Kinesiology, Louisiana State University, Baton Rouge, LA
- 3. Deborah Rees, Ph.D. degree, Department of Psychology, Louisiana State University, Baton Rouge, LA
- 4. Marney White, Ph.D. degree, Department of Psychology, Louisiana State University, Baton Rouge, LA
- 5. Dustin Dean, Ph.D. degree, Department of Animal Science, Louisiana State University, Baton Rouge, LA

CME Courses

- 1. Obesity Research Network, University of Kentucky. Consensus panel on obesity drug trial design, New Orleans, LA, 1997.
- 2. American Society of Bariatric Physicians. Obesity drugs, New Orleans, LA, 1997.
- 3. Obesity Research Network, University of Kentucky. Obesity drugs, New Orleans, LA, 1998.
- 4. American Society of Bariatric Physicians. Sibutramine San Francisco, CA, 1998.
- 5. Roche Pharmaceuticals, Primary Care Physicians. Orlistat, Pensacola, FL, 1999.
- 6. Roche Pharmaceuticals, Primary Care Physicians. Orlistat, Baton Rouge, LA, 1999.
- 7. Knoll Pharmaceuticals, Primary Care Physicians. Obesity treatment, Lake Charles, LA, 1999.
- 8. Roche Pharmaceuticals, Primary Care Physicians. Orlistat, Lake Charles, LA, 2000.
- 9. Louisiana Primary Care Association, Inc. Obesity as a chronic disease, Lake Charles, LA, 2000.
- 10. Torrance Memorial Medical Center. Trends and issues in diabetes, Torrance, CA, 2001.
- 11. The University of Kentucky Medical Center. Office management of endocrine problems: new horizons, Lexington, KY, 2001.
- 12. International Association for the Study of Obesity. Non-pharmacologic treatment of obesity: herbal aids to weight loss, Sao Paulo, Brazil, 2002.

13. Bissoon Institute of Mesotherapy. Lipolysis, W. Palm Bch., FL., 2003

revised 6/04